EXHIBIT

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Kimberly A. Dunne (SBN 142721)
kdunne@sidley.com
Michelle B. Goodman (SBN 218607)
mgoodman@sidley.com
Sean A. Commons (SBN 217603)
scommons@sidley.com
SIDLEY AUSTIN LLP
555 West Fifth Street, Suite 4000
Los Angeles, CA 90013
Telephone: (213) 896-6000
Facsimile: (213) 896-6600

Karen P. Hewitt (SBN 145309)
kphewitt@jonesday.com
Brian Hershman (SBN 168175)
bhershman@jonesday.com
JONES DAY
555 South Flower Street, Fiftieth Floor
Los Angeles, CA 90071
Telephone: (213) 489-3939
Facsimile: (213) 243-2539

Attorneys for Defendant Celgene Corporation
(*Additional Counsel listed on following page*)

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

UNITED STATES OF AMERICA, the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON, WISCONSIN, the DISTRICT OF COLUMBIA, and the CITY OF CHICAGO, Plaintiffs, *Ex rel.* BEVERLY BROWN, Plaintiff-Relator, v. CELGENE CORPORATION, Defendant.	Case No. 10-cv-03165 GHK (SSx) Assigned to: Hon. George H. King EXPERT SUPPLEMENTAL REBUTTAL REPORT OF LESLIE V. NORWALK

James C. Stansel (admitted *pro hac vice*)
jstansel@sidley.com
SIDLEY AUSTIN LLP
1501 K Street, NW
Washington, DC 20005
Telephone: (202) 736-8000
Facsimile: (202) 736-8711

Toni-Ann Citera (admitted *pro hac vice*)
tcitera@jonesday.com
Jennifer L. Del Medico
jdelmedico@jonesday.com
JONES DAY
222 East 41st Street
New York, New York 10017
Telephone: (212) 326-3939
Facsimile: (212) 755-7306

I. Background

1. I submitted a report on September 25, 2015 to address certain reimbursement policies of the Medicare and Medicaid programs administered by the Centers for Medicare and Medicaid Services ("CMS"). On October 26, 2015, I submitted a report in response to the September 25, 2015 report of Dr. Stephen Z. Fadem to respond to his claims regarding whether CMS-recognized compendia are reliable sources of support. This report is in response to Dr. Joel W. Hay's revised supplemental report submitted on April 22, 2016, which was further corrected on May 6, 2016 ("5/6/16 Hay Report").

2. The opinions offered in this report are based on my background, training, and experience described in my initial September 25, 2015 report ("Norwalk Initial Report"), which also attached my curriculum vitae as Exhibit A. My opinions have also been informed by my review of documents and other information cited in this report and referenced in Exhibit A.

3. As with my previous reports, the opinions herein are being offered in my capacity as an independent expert, not on behalf of CMS, the U.S. Department of Health & Human Services ("HHS"), or any other department or agency of the federal government. I do not purport to speak on behalf of any of these agencies, and I am not asserting that these opinions have been endorsed by them.

II. Summary of Opinions

4. Dr. Hay's 5/6/16 Report continues to rely upon assumptions and draw conclusions that, for reasons explained in my prior declarations, do not reflect how certain federal programs operate. This report will address a subset of defects in his analysis that I have identified since I submitted my Initial Report.

a. First, Dr. Hay alleges that the Medicare Advantage program (also known as Medicare Part C) incurred damages prior to the 2006 implementation of the Medicare Part D prescription drug benefit. According to Dr. Hay, these damages

purportedly came from the federal government reimbursing outpatient prescriptions as part of the Medicare Advantage program prior to 2006. In fact, the federal government did not reimburse outpatient prescriptions as part of the Medicare Advantage program before 2006 unless the drug was administered incident to a physician's services and therefore covered by the Medicare Part B program. Because Thalomid® and Revlimid® are oral medications, and thus not administered incident to a physician's services, these drugs were not covered by Medicare Part B. Therefore, contrary to Dr. Hay's belief, the federal government did not pay for Thalomid® and Revlimid® as part of the Medicare Advantage Program prior to 2006.[1]

b. Second, as I explained in my Initial Report, Medicare does not incur a cost based on any individual Part D covered prescription. CMS pays Part D Plans (and Medicare Advantage Plans offering outpatient prescription coverage since 2006) on a modified capitated basis. Under this model, Plans are paid a prospective, fixed payment at the beginning of the coverage period that is intended to cover all the reimbursable prescriptions and services provided to enrollees. The fixed payment does not vary based on the cost of any prescription or any service provided to an enrollee. Dr. Hay ignores this modified capitated structure and instead relies on Prescription Drug Event ("PDE") data that Plans provide to CMS. This PDE data reflects an unadjusted prescription cost that does represent the true cost to the Part D Plan because it does not account for rebates and other discounts. Moreover, the PDE data does not reflect or relate to the modified capitated payment from Medicare to a Plan.

[1] This lack of coverage for outpatient, self-administered prescriptions led to the Medicare Replacement Drug Demonstration ("MRDD") Project in 2004, which included Thalomid®, and eventually, Medicare Part D. *See* Norwalk Initial Report, ¶ 18.

c. Third, Dr. Hay includes all Medicare Part D off-label Thalomid® and Revlimid® prescriptions in his damages calculation. However, Part D Plans must cover certain off-label uses—those supported by compendia or CMS-recognized medical literature—and have discretion to cover other off-label uses. In addition to Part D Plans, Medicare's independent review contractor, Maximus, interprets what qualifies as adequate "support" to require coverage of off-label uses and has required Part D Plans to cover many of the off-label uses alleged in this case.

d. Fourth, Dr. Hay alleges that Celgene's donations to non-profit, independent patient assistance programs ("PAPs") are kickbacks when those donations are used to fund co-payment assistance for Medicare Part D beneficiaries. To ensure beneficiary access to drugs, HHS and CMS issued guidance in 2006 that referenced and incorporated guidance issued by the HHS Office of the Inspector General ("OIG") in 2005 reassuring manufacturers that, so long as certain criteria are met, they could donate to independent PAPs, which could, in turn, subsidize Part D co-payments. Indeed, CMS wanted to ensure that manufacturers did not stop donating to these PAPs because that would negatively impact beneficiary access to therapies.

III. Medicare Advantage / Medicare Part C

5. Dr. Hay alleges that Thalomid® prescriptions were reimbursed by Medicare, prior to the implementation of Medicare Part D, through the Medicare Advantage program, also known as Medicare Part C.[2] Dr. Hay cites to no data produced during this litigation or public sources showing that Medicare made payments for Thalomid® prescriptions during this time period. In fact, the federal government incurred no cost related to the prescription drug benefit of any Medicare Advantage Plan prior to 2006 for drugs such as Thalomid® and Revlimid®, which

[2] Dr. Hay acknowledges in his revised report that Revlimid® would not have been reimbursed by Medicare Advantage prior to 2006 because it was not FDA approved for marketing until late 2005.

were not covered under Medicare Part B because they were not provided incident to a physician service in a physician's office. *See* Norwalk Initial Report, ¶¶ 22, 25.

6. Medicare beneficiaries entitled to Medicare Part A (inpatient services) and enrolled in Part B (outpatient services) can choose to remain in these fee-for-service programs (meaning each individual service is reimbursed separately), or can opt into a managed care Medicare Advantage Plan (meaning CMS pays a private health plan a prospective, fixed per-beneficiary payment that does not vary based on the prescriptions or services provided) to receive the inpatient and outpatient services covered by Parts A and B.

7. Medicare Advantage Plans are operated by private health care entities such as insurers. Medicare pays these private entities a capitated (*i.e.*, fixed), per-enrollee rate to provide services to enrolled beneficiaries. Every Medicare Advantage Plan must provide services equal to those offered by traditional Medicare fee-for-service. In other words, Medicare Advantage Plans must cover everything covered by Medicare Parts A and B, though they have flexibility in how they provide those benefits and the patient cost-sharing amounts they require. Since 2006 and the implementation of Part D, most Medicare Advantage providers have offered at least one plan with a prescription drug benefit equivalent to Part D. Medicare subsidizes this drug benefit through Part D.

8. However, prior to 2006, Medicare did not subsidize outpatient prescription drug coverage unless the drug was covered under Part B. If Medicare Advantage Plans chose to cover drugs that were not covered by Part B, it was through a supplemental benefit that was not reimbursed by the federal government. *See* 65 Fed. Reg. 40170, 40206-07 (June 29, 2000) (explaining that supplemental benefits, including a drug benefit, are not covered by Medicare and are, instead, "fully paid for by [Medicare Advantage] enrollees through a separate premium or cost sharing."). Some Medicare Advantage Plans made prescription coverage a mandatory

supplemental benefit in addition to basic Medicare coverage, and others made it optional. In either case, the prescription drug benefit was fully paid by the Plan and beneficiary through separate co-insurance, such as a premium, deductible, or co-payment. *Id.* at 40206; *see also* 42 C.F.R. §§ 422.100, 422.2 (defining mandatory and optional supplemental benefits as "not covered by Medicare"). The federal government incurred no cost related to the prescription drug benefit of any Medicare Advantage Plan prior to 2006.

9. Since the implementation of Part D in 2006, prescription drugs offered through a Medicare Advantage Plan are covered through premiums paid in part by Medicare to the Medicare Advantage Plan and in part by the beneficiary through co-insurance fees in the same way as prescription drugs offered by Part D Plans. That is, prescriptions are reimbursed on a modified capitated basis. *See* Norwalk Initial Report, ¶¶ 54-57.

10. Dr. Hay incorrectly relies on PDE data in his 5/6/16 Report as the basis for calculating post-2006 Medicare Advantage and Part D damages. The PDE data is submitted to CMS by Medicare Advantage and Part D Plans and reflects the unadjusted cost to a Medicare Advantage or Part D Plan for a prescription. The PDE data does not reflect the net cost to the Plan because it does not account for discounts or any other price adjustments. In other words, it does not reflect what the Plans paid for the prescriptions and thus, does not reflect the actual cost to the government, including because the amount the government pays is not calculated on a per-drug basis.

IV. Medicare Part D

11. Dr. Hay misstates various aspects of the Medicare Part D program. I address two here: (1) his conclusion that all off-label uses of Thalomid® and Revlimid® resulted in damages; and (2) his allegation that Celgene's contributions to

non-profit patient assistance programs constitute kickbacks that resulted in false claims.

A. Medicare Part D Appeals

12. Dr. Hay's damages calculation for Medicare Part D encompass all off-label uses of Thalomid® and Revlimid®. As I explained in my Initial Report, many off-label uses are covered and reimbursed by Medicare Part D. Part D Plans must cover off-label, on-compendia uses, as well as off-label uses that are not supported by compendia but are supported by CMS-recognized literature. Norwalk Initial Report, ¶¶ 11, 58-60. Off-label uses can also be covered by Medicare Part D based on formularies or coverage policies, or on a case-by-case basis through prior authorization and appeals processes. Norwalk Initial Report, ¶¶ 62-63. These processes are implemented not only by individual Part D Plans, but also by CMS's contractor which reviews the decisions made by individual Plans.

13. Maximus is the independent review contractor that CMS employs—and has employed since the beginning of the Part D Program—to review appeals of drug coverage denials by Part D Plans, including Medicare Advantage Plans that offer the prescription drug benefit. In instances where an individual is denied coverage for a particular drug by a Part D Plan, the individual can appeal that decision, first to the Plan itself, and then to Maximus for a second review (and if needed, thereafter to an administrative law judge, an administrative review board, and ultimately, a judge in federal court). Appeals to Maximus follow particular procedures, as set forth in its Part D QIC Reconsideration Procedures Manual. Of particular note, appeals that require a medical necessity determination, including, for example, formulary exception requests and determinations of whether an off-label use is "medically accepted," are reviewed and decided by a board certified physician. *See* Maximus Federal Services, Part D QIC Reconsideration Procedures Manual, at 4 (Dec. 2014), available at

http://www.medicarepartdappeals.com/sites/default/files/PartD_ReconManual-v9.3.pdf; *see also* Medicare Prescription Drug Benefit Manual, Ch. 18 § 40.2.1 (explaining that a coverage determination based on clinical documentation such as unmet coverage criteria is considered a determination based on medical necessity). The physician's review is *de novo* and the appeal outcome is binding. If the appeal is decided in favor of the beneficiary, the Part D Plan must cover the drug at issue. *See* Medicare Prescription Drug Benefit Manual, Ch. 18 § 130.3.1 ("If the Part D Plan sponsor's decision is reversed in whole or in part by any other appeal entity, the Part D Plan sponsor must authorize or provide the benefit under dispute within 72 hours from the date it receives notice from the appeal entity reversing the determination.").

14. I have reviewed documents relating to appeals of Thalomid® and Revlimid® coverage decisions by Part D Plans that Maximus produced in this litigation subsequent to my Initial Report. Similar to the Part D Plans' appeals documents, some of which I referenced in my September 25, 2015 report, *see* Norwalk Initial Report, ¶ 76, the Maximus materials reflect that the government approves coverage for off-label uses, including off-label uses challenged in the Third Amended Complaint and Dr. Hay's 5/6/16 Report.

15. Maximus often requires documentation that a proposed off-label use is for a "medically accepted" indication with "support" in a compendia entry. Norwalk Initial Report, ¶ 31. The appeals show that, when determining what is "medically accepted," Maximus interprets the concept of "support" broadly. For instance, Maximus approved appeals and required coverage for off-label uses in the following circumstances:

a. Maximus found adequate support based on compendia entries that indicate an off-label use of Thalomid® is under investigation. *See* MAXIMUS089623-26 (requiring coverage for Thalomid® to treat renal cell cancer in May 2009 based on language from an AHFS entry that says the drug is "being

evaluated for the treatment of a variety of malignancies, including . . . renal carcinoma"); MAXIMUS105235-38 (requiring coverage for Thalomid® in September 2008 to treat ovarian cancer based on an AHFS entry that says the drug "is being evaluated for the treatment of a variety of malignancies, including. . . ovarian cancer ").

b. Maximus found adequate support based on a compendia entry indicating that Thalomid® *may* have activity in treating an off-label cancer, even though the entry indicates that Thalomid® should be used as a last resort. *See* MAXIMUS000633-36 (requiring coverage for Thalomid® to treat prostate cancer in May 2006 based on a USP-DI entry that says the drug "should be reserved for desperate clinical situations").

c. Maximus found adequate support based on compendia entries that do not meet the Medicare Benefit Policy Manual definition of "medical acceptance," such as DrugDex entries for Thalomid® with a III rating, even though the Medicare Benefit Policy Manual, Ch. 15, § 50.4.5.B states that "[a] use is not medically accepted by a compendium if the . . . indication is a Category 3 in NCCN or a Class III in DrugDex." *See* MAXIMUS036875-79 (requiring coverage for Thalomid® to treat mantle cell non-Hodgkin's lymphoma in August 2006 based on supportive language in a DrugDex entry with a III rating); MAXIMUS105845-49 (requiring coverage for Thalomid® to treat renal cancer in October 2008 based on a DrugDex entry with a III rating because the language related to renal cancer was supportive, and based on language in an AHFS entry stating that Thalomid® has been used in the treatment of renal cancer). Maximus also found adequate support where a disease was mentioned in DrugDex without any rating. *See* MAXIMUS111143-46 (covering Thalomid® to treat pancreatic cancer in November 2008 because the DrugDex entry said that the drug has "demonstrated efficacy in controlling malignancies including pancreatic cancer").

16. Maximus also has found adequate support for off-label uses based on medical literature. Appeals show that, similar to its treatment of compendia, Maximus has found adequate "support" in medical literature in situations where the Medicare Benefit Policy Manual's definition of what should be considered "supportive" of a "medically accepted" off-label use is not met. For instance, appeals were approved by Maximus requiring coverage for off-label uses as follows:

a. Maximus found adequate support based on medical literature describing a case report even though the Medicare Benefit Policy Manual, Ch. 15, §50.4.5.C provides that "case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs." *See* MAXIMUS118910-12 (requiring the Part D Plan to cover Revlimid® to treat acute myeloid leukemia in March 2009 based on a case report published in *Leukemia* in November 2006).

b. Maximus found adequate support based on medical literature describing a small, non-randomized trial even though the Medicare Benefit Policy Manual, Ch. 15, §50.4.5.C suggests that non-randomized studies require a "significant number" of subjects. *See, e.g.*, MAXIMUS145613-21 (requiring the Part D Plan to cover Thalomid® for chronic lymphocytic leukemia in September 2009 based on a 40-person trial published in *Leukemia* in May 2009).

c. Maximus found adequate support based on abstracts published in CMS-approved medical journals even though the Medicare Benefit Policy Manual, Ch. 15, §50.4.5.C states that "[a]bstracts (including meeting abstracts) are excluded from consideration." *See* MAXIMUS151397-401, 407-11 (requiring coverage for Revlimid® to treat prostate cancer in April 2010 based on two abstracts, one following the ASCO meeting, published in *Journal of Clinical Oncology* and *Cancer* in 2007).

17. In some instances where there is no support in recognized compendia or medical literature, Maximus has granted appeals and required coverage based on other evidence that supports an off-label use as reasonable and necessary for a particular patient. *See* MAXIMUS003296-31 (requiring coverage of Thalomid® to treat smoldering multiple myeloma without dexamethasone on July 14, 2006 because corticosteroids were contraindicated for the patient); MAXIMUS128572-76 (requiring coverage of Thalomid® to treat non-small cell lung cancer in July 2009 based on two ongoing clinical studies and the physician's statement that indicated the therapy was medically necessary, even though "[t]here are no citations in the Medicare approved compendia nor is there clinical research published in the Medicare approved publications that support the use of Thalomid (Thalidomide) for treatment of non-small cell lung cancer").

18. Through the appeals process, Maximus has required coverage for many of the off-label uses at issue in this matter. As indicated by the examples cited above, Maximus required coverage for Thalomid® to treat leukemia, lung cancer, lymphoma, multiple myeloma without dexamethasone, prostate cancer, pancreatic cancer, renal cancer, and ovarian cancer, and has required coverage for Revlimid® to treat leukemia and prostate cancer.

19. Additionally, Maximus has also ensured Part D Plans are providing coverage of "medically accepted" uses as defined by the Medicare Manual, namely, those uses that are supported by the CMS-recognized compendia and literature, within the corresponding parameters set out in the Manual. Specifically, in addition to the indications already discussed, Maximus has required coverage for Thalomid® to treat brain cancer, Kaposi's sarcoma, melanoma, and MDS. *See, e.g.*, MAXIMUS038349-53 (requiring a Part D Plan to cover Thalomid® to treat MDS on November 8, 2006 based on a supportive DrugDex entry); MAXIMUS080854-59 (requiring a Part D Plan to cover Thalomid® on January 26, 2008 for the treatment of glioblastoma

multiforme brain cancer based on a supportive DrugDex entry); MAXIMUS047672-77 (requiring a Part D Plan to cover Thalomid® in September 2006 for the treatment of malignant melanoma based on a supportive DrugDex entry); MAXIMUS138944-47 (requiring coverage of Thalomid® on November 7, 2009 to treat AIDS-related Kaposi's sarcoma based on a supportive DrugDex entry).

20. Likewise, Maximus has required coverage for Revlimid® to treat lymphoma, first-line multiple myeloma, MDS without del-5Q deletion, and myelofibrosis. *See* MAXIMUS115411-14, 426-29 (requiring the Part D Plan to cover Revlimid® to treat mantle cell non-Hodgkin's lymphoma in January 2009 based on a October 20, 2008 *Journal of Clinical Oncology* article); MAXIMUS029029-33 (requiring coverage for Revlimid® as treatment for first-line multiple myeloma on June 3, 2014 based on a supportive NCCN entry); MAXIMUS117626-29 (requiring coverage for Revlimid® as treatment for MDS without a del-5Q deletion on February 26, 2009 based on a supportive NCCN entry and research published the year before in *Blood,* a Medicare-approved journal); and MAXIMUS118659-62 (requiring coverage in March 2009 for Revlimid® to treat myelofibrosis based on an article published in *Blood* on August 15, 2006).

B. Non-Profit Patient Assistance Programs

21. Dr. Hay asserts in his 5/6/16 Report that Celgene's contributions to charitable patient assistance foundations, including the Patient Access Network Foundation ("PANF") and the Chronic Disease Fund ("CDF"), constitute kickbacks. Dr. Hay appears to misunderstand the Agency's guidance on this subject. Specifically, he appears to believe based on his review of OIG guidance and conversations with Relator's counsel that it violates the Anti-Kickback Statute if a pharmaceutical company's donations to a non-profit, independent patient assistance program ("PAP") are used to cover Medicare Part D co-payments. 5/6/16 Hay Report, ¶ 120. According to Dr. Hay, this is "illegally fund[ing] patient co-pays." *Id.*

at ¶ 74. He goes on to say that it is "clearly" in Celgene's financial interest to assist with a Medicare co-pay if, as a result, "Celgene got back the Medicare payment portion (*e.g.*, 80% of a Revlimid® prescription cost)." *Id.* at ¶ 119.

22. Dr. Hay's description of how charitable kickbacks could create financial incentives for manufacturers or increase government costs does not accurately describe Medicare coverage.

a. Under Medicare ***Part B***, a patient's co-payment is typically 20 percent with Medicare covering the remaining 80 percent of the cost. That is not the case for Medicare Part D. Individual Part D Plans set beneficiaries' cost-sharing responsibilities. These cost-sharing amounts can vary significantly from one Part D Plan to the next, or within a Plan depending on a variety of factors such as whether the drug is listed on the Plan's formulary and where the beneficiary falls in the coverage spectrum (*e.g.*, if they are in the "donut hole," which is the coverage gap that occurs after a beneficiary hits his or her initial spending limit, versus receiving catastrophic coverage after the donut hole).

b. Drug manufacturers, including Celgene, negotiate drug prices, rebates, and any other discounts with various entities, including Part D Plans, pharmacies, pharmacy benefits managers, and others that reduce the cost of a prescription; the cost of a Thalomid® or Revlimid® prescription is therefore different from one Plan to the next, and the payment to Celgene is not dependent on the co-payment amount.

c. As discussed in my Initial Report, the cost of Thalomid®, Revlimid®, or any Part D covered drug to a Plan is not directly passed through to Medicare. *See* Norwalk Initial Report, ¶¶ 54-57; *see also* Email from Eden Heard, HHS Office of General Counsel, CMS Division, to Justin Brooks et al. (January 20, 2016) (noting "[i]n the case of Medicare Part D, we don't pay on a claim basis …. The government cost is not determined at the [point of sale] but is determined in the

annual Part D payment reconciliation. The reconciliation occurs at the [Part D Plan] level, not the claim level.") (attached as Exhibit B). Part D Plans are paid on a prospective, modified capitated basis, and those payments do not vary or depend on the cost of any individual prescription. Norwalk Initial Report, ¶¶ 54-55. Thus, Medicare is not responsible for the cost of a Part D prescription minus the co-payment amount as suggested by Dr. Hay.

23. Contrary to Dr. Hay's views about OIG guidance from 2014, HHS, the OIG, and CMS have stated that manufacturers may make donations to *bona fide* charitable organizations, and those donations may be used to fund Medicare Part D beneficiaries' co-payments so long as certain criteria are met. The 2014 guidance cited by Dr. Hay also states that "Independent Charity PAPs provide a valuable resource to financially needy patients." 79 Fed. Reg. 31120, 31123 (May 30, 2014). The OIG reminds stakeholders that "[l]ongstanding OIG guidance, including [a] 2005 [special advisory bulletin], makes clear that pharmaceutical manufacturers can effectively contribute to the safety net by making cash donations to independent, *bona fide* charitable assistance programs." *Id.* at 31121.

24. By way of background, as CMS prepared for the launch of the Medicare Part D program, ensuring continued access to drugs for the financially needy was a major concern. Prior to Part D, Medicare beneficiaries of limited means could receive prescription drugs through manufacturer and independent charity PAPs at little or no cost. Since most prescription drugs were not available through Medicare, these PAPs did not raise anti-kickback considerations under Medicare because there was little to no impact (or potential impact) on Medicare spending. However, once Congress approved the Medicare prescription drug benefit, manufacturers, independent charities, and beneficiaries that had long supported, operated, or relied on PAPs to help patients obtain their medications began to worry that the Anti-Kickback Statute

might be interpreted to limit the availability of subsidized prescriptions for Part D beneficiaries.

25. In 2005, OIG issued its initial guidance on manufacturer-run and independent, non-profit PAPs. 70 Fed. Reg. 70623 (November 22, 2005). Just three months after OIG's advisory bulletin, the Secretary of HHS issued a statement to "clarify any confusion that may exist." In a letter to the CEO of PhRMA, the trade association for pharmaceutical companies, Secretary Leavitt stated that "nothing in the law prevents pharmaceutical companies from continuing to support" independent PAPs. *See* Letter from Michael O. Leavitt, Secretary of HHS, to Billy Tauzin, President and CEO of PhRMA (February 9, 2006) (attached as Exhibit C).

26. Secretary Leavitt's letter to PhRMA pointed to OIG's special advisory bulletin, in which OIG spelled out five guideposts for "properly structured" independent PAPs:

a. A pharmaceutical manufacturer cannot directly or indirectly influence or control the independent PAP.

b. The PAP must award assistance in an independent manner such that the assistance provided cannot be attributed to a manufacturer.

c. The PAP must award assistance without regard to manufacturers' interests and without consideration of the patient's choice of product, provider, practitioner, supplier, or Part D Plan.

d. The PAP must award assistance based on verified financial need using uniform measures applied in a consistent manner.

e. The PAP cannot provide manufacturers with data that allows a manufacturer to correlate the amount or frequency of its donations with the number of subsidized prescriptions for its products. (Though, PAPs are allowed to provide aggregate data to donors about the number of patients per disease state receiving assistance.) *See* 70 Fed. Reg. at 70626.

27. Just a few months after the Secretary's letter to pharmaceutical companies, CMS issued its own official guidance stating that manufacturers could continue to support properly structured "independent PAPs operated by bona fide public charities." CMS, Memorandum re: HPMS Q&A - Patient Assistance Programs (October 4, 2006), at 4 (attached as Exhibit D).

28. According to the OIG, Secretary Leavitt, and CMS, so long as the five factors articulated in the 2005 OIG Guidelines are satisfied, manufacturers can contribute to independent PAPs, which can provide co-payment assistance to Part D beneficiaries.

29. During my time at CMS, determining whether an independent PAP was properly structured and the OIG criteria met was a legal analysis within the purview of the OIG, and my understanding is that it remains so today. *See* CMS, Perspective on Pharmaceutical Company Patient Assistance Programs, at 2 (January 25, 2006), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2006/CMSPAP.pdf. As a result, this report does not opine on the application of those five factors to the facts of this case, beyond noting that Dr. Hay does not appear to identify any evidence that the five factors were violated by Celgene, CDF, PANF, or any other independent PAP or specific findings or guidance by the OIG prohibiting the types of contracts between Celgene and PAPs, such as CDF and PANF.

30. Since the inception of the Part D program, HHS—from the Secretary down—has been invested in ensuring that independent PAPs continue to receive donations from manufacturers and are able to use those donations to subsidize Part D prescriptions for the benefit of patients.

Dated: June 3, 2016 By: _____
Leslie V. Norwalk

Exhibit A

EXHIBIT A
MATERIALS CONSIDERED

Court Documents:

Expert Report of Joel W. Hay, *United States of America, et al., ex rel. Beverly Brown v. Celgene Corporation*, Case No. 10-cv-03165, United States District Court, Central District of California – Western Division, September 25, 2015.

Revised Supplemental Expert Report of Joel W. Hay, *United States of America, et al., ex rel. Beverly Brown v. Celgene Corporation*, Case No. 10-cv-03165, United States District Court, Central District of California – Western Division, April 22, 2016.

Revised Supplemental Expert Report of Joel W. Hay (Corrected), *United States of America, et al., ex rel. Beverly Brown v. Celgene Corporation*, Case No. 10-cv-03165, United States District Court, Central District of California – Western Division, May 6, 2016.

Expert Report of Leslie V. Norwalk, *United States of America, et al., ex rel. Beverly Brown v. Celgene Corporation*, Case No. 10-cv-03165, United States District Court, Central District of California – Western Division, September 25, 2015.

Rebuttal Expert Report of Leslie V. Norwalk, *United States of America, et al., ex rel. Beverly Brown v. Celgene Corporation*, Case No. 10-cv-03165, United States District Court, Central District of California – Western Division, October 26, 2015.

Bates-Stamped Documents:

MAXIMUS000633-36

MAXIMUS003296-31

MAXIMUS029029-33

MAXIMUS036875-79

MAXIMUS038349-53

MAXIMUS047672-77

MAXIMUS080854-59

MAXIMUS089623-26

MAXIMUS105235-38

MAXIMUS105845-49

MAXIMUS111143-46

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MAXIMUS115411-14

MAXIMUS115426-29

MAXIMUS117626-29

MAXIMUS118659-62

MAXIMUS118910-12

MAXIMUS128572-76

MAXIMUS138944-47

MAXIMUS145613-21

MAXIMUS151397-401

MAXIMUS151407-11

Statutes and Regulations:

42 C.F.R. § 422.100

42 C.F.R. § 422.2

Publicly Available Materials:

65 Fed. Reg. 40170 (June 29, 2000)

70 Fed. Reg. 70623 (Nov. 22, 2005)

79 Fed. Reg. 31120 (May 30, 2014)

CMS, Medicare Benefit Policy Manual, Ch. 15, § 50.4.5 (Rev. 96) (Oct. 24, 2008), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf.

CMS, Memorandum re: HPMS Q&A - Patient Assistance Programs (Oct. 4, 2006), https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/MemoPAPsOutsidePartDBenefit_100406.pdf.

CMS, Perspective on Pharmaceutical Company Patient Assistance Programs (Jan. 25, 2006), http://oig.hhs.gov/fraud/docs/alertsandbulletins/2006/CMSPAP.pdf.

EXHIBIT A
MATERIALS CONSIDERED

CMS, Medicare Prescription Drug Benefit Manual, Ch. 18 § 40.2.1 (Rev. 9) (Feb. 22, 2013), https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/index.html?redirect=/medprescriptdrugapplgriev/13_forms.asp.

CMS, Medicare Prescription Drug Benefit Manual, Ch. 18 § 130.3.1 (Rev. 2) (June 22, 2006), https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/downloads/partdmanualchapter18.pdf.

Email from Eden Heard, HHS Office of General Counsel, CMS Division, to Justin Brooks *et al.* (Jan. 20, 2016)

Letter from Michael O. Leavitt, Secretary of HHS, to Billy Tauzin, President and CEO of PhRMA (Feb. 9, 2006), http://oig.hhs.gov/fraud/docs/alertsandbulletins/2006/TauzinPAP.pdf.

Maximus Federal Services, Part D QIC Reconsideration Procedures Manual (Dec. 2014), http://www.medicarepartdappeals.com/sites/default/files/PartD_ReconManual-v9.3.pdf.

Exhibit B

From: Heard, Eden (HHS/OGC) [mailto:Eden.Heard@hhs.gov]
Sent: Wednesday, January 20, 2016 10:22 AM
To: Justin Brooks; Stansel, James C.; Dunne, Kimberly A.; Olson, William E. (CIV) (William.E.Olson@usdoj.gov)
Cc: Johnson, Amanda S. (CMS/CM); Allen, Karen M. (CMS/OTS); Horton, Dinah L. (CMS/OTS)
Subject: FW: Celgene - final action question - response to example provided

Amanda Johnson has provided written responses below. We can still have a call at 11 a.m. on Friday if you think it's necessary, and if that works for Will and Sidley.

Eden Heard
HHS/OS/OGC, CMS Division
(202) 401-7418

From: Justin Brooks [mailto:JBrooks@gbblegal.com]
Sent: Friday, January 15, 2016 10:25 AM
To: Heard, Eden (HHS/OGC); 'jstansel@sidley.com'; 'kdunne@sidley.com'
Cc: Olson, William E. (CIV) (William.E.Olson@usdoj.gov); mwilliams@bmkattorneys.com
Subject: RE: Celgene - final action question - response to example provided

Thank you, Eden. We'd like final clarification and/or confirmation on the below points as soon as it's possible for CMS to do so. We need this to rerun our numbers and produce an accurate supplemental report. We are happy to schedule a final call with our experts, your team, and Celgene's experts if necessary to reach final resolution.

1) In the data set provided, there are 2,269 bene_ids were associated with both "H" (Local Medicare Advantage Prescription Drug (MA-PD) Plans) and "S" Prescription Drug Plans (PDP). How should we deal with the patients with multiple plan types?

> CMS response: Low-income beneficiaries can change plans at any time. In addition, other beneficiaries may be granted a special enrollment period in which they change plans. Any change in plans will become effective at the beginning of the month because enrollment

can only change on a monthly basis. The contract of record is responsible for the beneficiary claims with DOS that occur during the time the beneficiary is enrolled in its plan.

2) According to the table,

"H" for Local Medicare Advantage Prescription Drug (MA-PD) Plans,

"R" for Regional MA-PD Plans,

"S" for Prescription Drug Plans (PDP),

"E" for Employer Group Waiver Plans (EGWP),

"X" for LI NET plan.

Should we consider "H" and "R" as MA patients and the rest ("S", "E" and "X") as non MA patients?

CMS response: H and R represent the MA plans and the others are the stand alone PDPs.

3) How do we identify the final paid claim by Medicare when we see multiple claims for a patient per service date (even if we see that these claims are due to claims submitted by different service providers)?

CMS response: The final “paid” claim will be identified with a CLM_FINL_ACTN_IND of “Y” and either a 1 (original), 2 (adjusted), or 4 (resubmitted) in the CLM_TYPE_CD field. Claims with a CLM_FINL_ACTN_IND of “Y” and a CLM_TYPE_CD of “4” are deleted PDEs and were not included in the annual Part D payment reconciliation. In the case of Medicare Part D, we don’t pay on a claim basis so the claims with a CLM_FINL_ACTN_IND of “Y” and either a 1 (original), 2 (adjusted), or 4 (resubmitted) in the CLM_TYPE_CD field are the claims that were part of the annual Part D payment reconciliation.

4) For 3) above, when different payment amounts are seen for multiple claims for a patient per service date, how to identify the final claim amount paid?

CMS response: The total cost of the drug will be the sum of GDCB and GDCA. The PDE provides a breakdown of what the plan (CPP and NPP) and the beneficiary (Pt. Pay amount) paid at the point-of-sale. The government cost is not determined at the POS but is determined in the annual Part D payment reconciliation. The reconciliation occurs at the PBP level, not the claim level.

Justin S. Brooks
Guttman, Buschner & Brooks PLLC
1515 Locust Street, Suite 501
Philadelphia, PA 19102
Direct Dial: (302) 327-9210
Mobile: (610) 547-9556
jbrooks@gbblegal.com

From: Heard, Eden (HHS/OGC) [mailto:Eden.Heard@hhs.gov]
Sent: Monday, January 11, 2016 2:25 PM
To: 'jstansel@sidley.com' <jstansel@sidley.com>; Justin Brooks <JBrooks@gbblegal.com>; 'kdunne@sidley.com' <kdunne@sidley.com>
Cc: Olson, William E. (CIV) (William.E.Olson@usdoj.gov) <William.E.Olson@usdoj.gov>
Subject: Celgene - final action question - response to example provided

The CMS Integrated Data Repository (IDR) views this one PDE as four different PDEs because of the Rptd Service Provider ID, in which the sponsor submitted a different Service Provider ID in each submission. Was this the only instance like this that you found? There are key fields on the PDE that the IDR uses to classify PDEs into families (families are the summary of changes to one PDE). Because of the slight variation in the Service Provider ID, the IDR classifies this as four different PDEs but it is really only one PDE. We don't know how often this occurs. As stated previously, there is only one final action PDE in a family. This is a situation in which IDR thinks there are four different families.

Date of Service	Rx Service Reference Number	Fill Number	Rptd Service Provider ID	Rptd Service Provider ID Qlfyr	Dispensing Status Code	Claim Effective Indicator
5/4/2007	000000003546	1	PAPERCLAIM	99		Y
5/4/2007	000000003546	1	4541416	07		Y
5/4/2007	000000003546	1	PAPER CLM	99		Y
5/4/2007	000000003546	1	PAPER CLAIM	99		Y

Eden Heard
HHS/OGC/CMS Division
(202) 401-7418

Exhibit C

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

FEB - 9 2006

The Honorable Billy Tauzin
President and CEO
The Pharmaceutical Research and Manufacturers of America
1100 Fifteenth Street, NW
Washington, DC 20005

Dear Mr. Tauzin:

Pharmaceutical companies' patient assistance programs (PAPs) have proven to be a vital source of medication for many Americans. However, there has been concern about federal laws and regulations affecting pharmaceutical companies' ability to continue these programs with the advent of the Medicare prescription drug benefit. I wanted to take this opportunity to clarify any confusion that may exist.

As you know, the decision to operate a PAP is up to each pharmaceutical company, not the United States Government. The terms and conditions are determined by the company, without government involvement. Recent guidance from the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG) make clear that lawful opportunities exist to provide drug assistance to Medicare beneficiaries. This guidance is attached for your review.

Specifically, PAPs can continue to assist Part D enrollees through a properly structured program that operates entirely outside the Part D benefit. Under this approach, the beneficiary does not use his or her Part D benefit to obtain the drug and the cost of the drug is not applied toward the enrollee's true out-of-pocket costs.

Other opportunities exist as well. Many pharmaceutical companies have donated to bona fide independent charities that operate PAPs that serve financially needy Medicare and other patients. Nothing in the law prevents pharmaceutical companies from continuing to support these vital programs.

The recent OIG guidance clearly supports the continuation of assistance by pharmaceutical company PAPs for needy Medicare beneficiaries and provides guidance on properly structuring such arrangements, including programs operating outside Part D.

Again, HHS recognizes the value of pharmaceutical PAPs to their clients, including Medicare beneficiaries. It is my hope that HHS and PhRMA can work together to create opportunities for the Medicare drug benefit and PAPs to work in tandem.

Sincerely,

Michael O. Leavitt

Enclosures

it to the agency. Thus, each firm submitting a compliance extension request will need 5 hours of employee time to complete the request. Given that 56 businesses are expected to submit written requests in year one, the total burden hours for year one are 280.

In year two, FDA expects about one-half as many firms to request a labeling compliance extension. So for year two, 28 firms are expected to file a request for an extension to the labeling compliance date. Again, assuming that it will take 5 hours to complete each request, the total burden hours for year two will be 140.

Dated: November 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23040 Filed 11–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0343]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Requesting an Extension to Use Existing Label Stock after the *Trans* Fat Labeling Effective Date of January 1, 2006" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing an opportunity for public comment on this collection of information. Since this collection received emergency approval that expires on January 1, 2006, FDA is following the normal PRA clearance procedures by issuing that notice.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 1, 2005 (70 FR 52108), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0571. The approval expires on January 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: November 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23041 Filed 11–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: December 12, 2005, 9 a.m.—5 p.m., EST.

Place: Audio Conference Call and Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Monday, December 12, from 9 a.m. to 5 p.m. The public can join the meeting in person at the address listed above or by audio conference call by dialing 1–800–369–6048 on December 12 and providing the following information:

Leader's Name: Dr. Geoffrey Evans.

Password: ACCV.

Agenda: The agenda items for the December meeting will include, but are not limited to: A summary of the U.S. Court of Federal Claims' 18th Judicial Conference; a report from the ACCV Workgroup looking at proposed guidelines for future changes to the Vaccine Injury Table; and updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice, National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics and Evaluation Research (Food and Drug Administration). Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail *clee@hrsa.gov.* Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. These persons will be allocated time as it permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, DVIC, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–2124 or e-mail *clee@hrsa.gov.*

Dated: November 15, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–23042 Filed 11–21–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: OIG periodically develops and issues guidance, including Special Advisory Bulletins, to alert and inform the health care industry about potential problems or areas of special interest. This **Federal Register** notice sets forth the recently issued OIG Special Advisory Bulletin addressing patient assistance programs for Medicare Part D enrollees.

FOR FURTHER INFORMATION CONTACT: Darlene M. Hampton, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees (November 2005)

I. Introduction

Patient assistance programs (PAPs) have long provided important safety net assistance to patients of limited means

who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs. PAPs are structured and operated in many different ways. PAPs may offer cash subsidies, free or reduced price drugs, or both. Some PAPs offer assistance directly to patients, while others replenish drugs furnished by pharmacies, clinics, hospitals, and other entities to eligible patients whose drugs are not covered by an insurance program. Some PAPs are affiliated with particular pharmaceutical manufacturers; others are operated by independent charitable organizations (such as, for example, patient advocacy and support organizations) without regard to any specific donor or industry interests.

Many pharmaceutical manufacturers have historically sponsored PAPs that assist patients whose outpatient prescription drugs are not covered by an insurance program (including some Medicare beneficiaries), in obtaining the manufacturer's products for free or at greatly reduced cost. Beginning on January 1, 2006, Medicare Part D will offer Medicare beneficiaries who elect to enroll broad coverage for outpatient prescription drugs. Accordingly, Medicare beneficiaries who enroll in Part D will no longer qualify under traditional PAP eligibility criteria. Part D enrollees will incur cost-sharing obligations (including deductibles and copayments), although many low-income beneficiaries will qualify for subsidies that will reduce or eliminate their financial obligations.[1] Pharmaceutical manufacturers have expressed interest in continuing to assist Medicare Part D enrollees of limited means who do not qualify for the low-income subsidy.

OIG is mindful of the importance of ensuring that financially needy beneficiaries who enroll in Part D receive medically necessary drugs, and OIG supports efforts of charitable organizations and others to assist financially needy beneficiaries, as long as the assistance is provided in a manner that does not run afoul of the Federal anti-kickback statute or other laws.[2] We have been asked whether the anti-kickback statute will be implicated if pharmaceutical manufacturer PAPs[3] continue to offer assistance to financially needy Medicare beneficiaries who enroll in Part D by subsidizing their cost-sharing obligations for covered Part D drugs. For the reasons set forth below and consistent with extant OIG guidance, we conclude that pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts present heightened risks under the anti-kickback statute. However, in the circumstances described in this Bulletin, cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions. In addition, we believe other arrangements described in this Bulletin, if properly structured, may pose reduced risk. Thus, we believe lawful avenues exist for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs.

Given the importance of ensuring continued access to drugs for beneficiaries of limited means and the expedited time frame for implementation of the Part D benefit, we are issuing this Special Advisory Bulletin to identify potentially abusive PAP structures, as well as methods of providing assistance that mitigate or vitiate the potential for fraud and abuse. This Special Advisory Bulletin draws on the government's prior fraud and abuse guidance and enforcement experience. However, because the Part D benefit has not yet begun, and any assessment of fraud and abuse is necessarily speculative, this Bulletin cannot, and is not intended to, be an exhaustive discussion of relevant risks or beneficial practices.

At the outset, it is important to note the following:

- PAPs need not disenroll all Medicare beneficiaries from their existing PAPs to be compliant with the fraud and abuse laws. Enrollment in Part D is voluntary; therefore, existing PAPs may continue to provide free or reduced price outpatient prescription drugs to Medicare beneficiaries who have not yet enrolled in Part D. The Centers for Medicare & Medicaid Services (CMS) anticipates instituting procedures that will help PAPs determine if PAP clients have enrolled in Part D.
- Occasional, inadvertent cost-sharing subsidies provided by a pharmaceutical manufacturer PAP to a Part D enrollee should not be problematic under the anti-kickback statute (*e.g.*, where, despite due diligence, a pharmaceutical manufacturer PAP does not know and should not have known that a beneficiary has enrolled in Medicare Part D).
- Nothing in the Part D program or in any OIG laws or regulations prevents pharmaceutical manufacturers or others from providing assistance (*e.g.*, through cash subsidies or free drugs) to uninsured patients. Nothing in this Bulletin impacts programs that assist uninsured patients.
- Nothing in this guidance should be construed as preventing pharmacies from waiving cost-sharing amounts owed by a Medicare beneficiary on the basis of a good faith, individualized assessment of the patient's financial need (or failure of reasonable collection efforts), so long as the waiver is neither routine, nor advertised. Financial need-based waivers that meet these criteria have long been permitted.[4] However, a pharmacy has not waived a cost-sharing amount if the amount has been paid to the pharmacy, in cash or in kind, by a

[1] *See* 42 CFR 423.782.

[2] This Bulletin focuses on the application of the Federal anti-kickback statute. Other potential risk areas, including, for example, potential liability under the False Claims Act, 31 U.S.C. 3729–33, or other Federal or State laws, are not addressed here. Moreover, this Bulletin focuses on arrangements that involve pharmaceutical manufacturers directly or indirectly subsidizing Part D cost-sharing amounts. Programs that subsidize Part D premium amounts pose risks under the anti-kickback statute that are not addressed here. Similarly, PAPs established by health plans that subsidize cost sharing or premium amounts under Part D raise different issues and may require a different analysis. While this Bulletin may provide some useful guidance for other kinds of PAP arrangements, such PAPs are not specifically considered here.

[3] For purposes of this Special Advisory Bulletin, a pharmaceutical manufacturer PAP includes any PAP that is directly or indirectly operated or controlled in any manner by a pharmaceutical manufacturer or its affiliates (including, without limitation, any employee, agent, officer shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)). Moreover, for purposes of an anti-kickback analysis, we would not consider a charitable foundation (or similar entity) formed, funded or controlled by a manufacturer or any of its affiliates (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) to be a *bona fide*, independent charity, because interposition of the entity would not sever the nexus between the patient subsidies and the manufacturer. Indeed, in most cases, the foundation would receive all of its funding from the pharmaceutical manufacturer (or its affiliates) and would provide subsidies only for the manufacturer's products.

[4] *See, e.g.*, section 1128A(i)(6)(A) of the Act; OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, August 2002, *http:oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf*. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included a safe harbor specifically incorporating these criteria for waivers of cost-sharing amounts for Part D drugs. Additionally, the safe harbor protects cost-sharing waivers offered to individuals who qualify for the low income subsidy, even if the waivers are routine and do not follow an individualized determination of financial need, provided they are not advertised. *See* Section 1860D–42 of MMA, codified at 42 U.S.C. 1320a–7b(b)(3)(G).

third party (including, without limitation, a PAP).

II. The Federal Anti-Kickback Statute

The Federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act),[5] makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any Federal health care program, including Medicare and Medicaid. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. OIG may also initiate administrative proceedings to exclude a person from Federal health care programs or to impose civil money penalties for kickback violations under sections 1128(b)(7) and 1128A(a)(7) of the Act.[6]

A determination regarding whether a particular arrangement violates the anti-kickback statute requires a case-by-case evaluation of all of the relevant facts and circumstances, including the intent of the parties. For PAPs, the nature, structure, sponsorship, and funding of the particular PAP are necessarily relevant to the analysis.

III. Patient Assistance Programs

As described more fully below, cost-sharing subsidies provided by pharmaceutical manufacturer PAPs pose a heightened risk of fraud and abuse under the Federal anti-kickback statute. However, there are non-abusive alternatives available. In particular, as discussed below, pharmaceutical manufacturers can donate to *bona fide* independent charity PAPs, provided appropriate safeguards exist. Moreover, this Bulletin discusses several other alternatives that may pose a reduced risk of fraud and abuse.

This section addresses in turn: pharmaceutical manufacturer PAPs, independent charity PAPs, manufacturer PAPs that operate "outside of Part D"; "coalition model" PAPs, and bulk replacement programs.

A. Pharmaceutical Manufacturer PAPs

Analytically, pharmaceutical manufacturer PAPs raise two main issues in connection with the Part D program: (i) Whether subsidies they provide can count toward a Part D enrollee's true out-of-pocket costs (known as the TrOOP); and (ii) whether the subsidies implicate the Federal anti-kickback statute.[7]

As to the first issue, the Part D regulations make clear that beneficiaries may count toward their TrOOP assistance received from any source other than group health plans, other insurers and government funded health programs, and similar third party payment arrangements.[8] The preamble to the Part D regulations explains that cost-sharing assistance furnished by a PAP, including a manufacturer PAP, will count toward a beneficiary's TrOOP expenditures, even if the PAP does not comply with the fraud and abuse laws.[9] This approach relieves beneficiaries of the financial risk of accepting assistance from an entity that may be improperly structured or operated.

As to the second issue, the core question is whether the anti-kickback statute would be implicated if a manufacturer of a drug covered under Part D were to subsidize cost-sharing amounts (directly or indirectly through a PAP) incurred by Part D beneficiaries for the manufacturer's product. Consistent with our prior guidance addressing manufacturer cost-sharing subsidies in the context of Part B drugs,[10] we believe such subsidies for Part D drugs would implicate the anti-kickback statute and pose a substantial risk of program and patient fraud and abuse.[11] Simply put, the subsidies would be squarely prohibited by the statute, because the manufacturer would be giving something of value (*i.e.*, the subsidy) to beneficiaries to use its product. Where a manufacturer PAP offers subsidies tied to the use of the manufacturer's products (often expensive drugs used by patients with chronic illnesses), the subsidies present all of the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries= incentives to locate and use less expensive, equally effective drugs.

It is impossible to predict with certainty the way in which abuse may occur in a new benefit program that is not yet operational. The following are illustrative examples of some types of abuse that may occur:

- Increased costs to the program. We are concerned that a manufacturer might use beneficiary cost-sharing subsidies, which help beneficiaries meet their TrOOP requirement, to increase the number of beneficiaries using the manufacturer's product who reach the

[5] 42 U.S.C. 1320a–7b(b).

[6] 42 U.S.C. 1320a–7(b)(7); 42 U.S.C. 1320a–7a(a)(7).

[7] In some cases, a subsidy for Part D cost-sharing obligations provided by a pharmaceutical manufacturer may also implicate the prohibition on offering inducements to beneficiaries, as set forth in section 1128A(a)(5) of the Act, if the subsidy is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier, such as a physician or pharmacy. We have interpreted "provider, practitioner, or supplier" to exclude pharmaceutical manufacturers unless they also own or operate pharmacies, pharmaceutical benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs. *See* Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, supra note 4.

[8] *See* 42 CFR 423.100; 42 CFR 423.464; 70 FR 4194, 4239 (January 28, 2005). We note that CMS is the proper agency to address questions about the mechanics of calculating TrOOP. In certain circumstances, knowing improper TrOOP calculations may give rise to liability under the False Claims Act, 31 U.S.C. 3729–33.

[9] *See* 70 FR 4194 at 4239.

[10] *See, e.g.*, OIG Advisory Opinion Nos. 02–13 and 03–3 (unfavorable opinions involving proposals from pharmaceutical manufacturer PAPs to subsidize Part B cost-sharing amounts). We note that the cost and utilization management features of the Part D program, while important, do not sufficiently mitigate the risks.

[11] Some in the industry have asserted that cost-sharing subsidies for Part D drugs differ from cost-sharing subsidies for Part B drugs so long as the subsidies are given to patients who are in a Part D "coverage gap" (*i.e.*, a benefit period during which the beneficiary pays 100% of the cost of the drugs). To support their position, they contend either that beneficiaries in the coverage gap are functionally "uninsured" or that the situation is comparable to providing free drugs to financially needy beneficiaries so long as no Federal health care program is billed for all or part of the drug, a practice we previously permitted in the context of subsidies for Part B drugs. *See* OIG Advisory Opinion Nos. 02–13 and 03–3. Under Part D, a "coverage gap" is a period of insurance coverage. *See* CMS Frequently Asked Question ID 4855, *http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=4855* (regarding prescription drug benefit coordination of benefits and TrOOP). During the coverage gap, beneficiaries remain enrolled in their Part D plans and have a continuing obligation to pay Part D premiums; Part D plans continue to receive the monthly per-enrollee direct subsidy from the Medicare program. Moreover, subsidies during the coverage gap are not like furnishing free drugs where no Federal health care program is billed. Sufficient spending during the coverage gap qualifies the beneficiary to reach the catastrophic coverage portion of the Part D benefit, at which point the Medicare program resumes payment for most of the costs of the beneficiary's drugs. In this regard, the different structures of the Part B and Part D benefits are crucial to the analysis.

catastrophic benefit in any given coverage year and to hasten the point during the coverage year at which beneficiaries reach the catastrophic benefit. This is of particular import because Medicare will make cost-based payments during the catastrophic coverage benefit.[12] We know from experience that cost-based reimbursement is inherently prone to abuse, including by vendors that sell products reimbursed on a cost basis. Similarly, we are concerned about the use of cost-sharing subsidies to shield beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices. Inflated prices could have a "spillover" effect on the size of direct subsidies, reinsurance payments, and risk corridor payments paid by Medicare to Part D plans in future years,[13] potentially resulting in higher costs to the Medicare program.

• Beneficiary steering and anti-competitive effects. Subsidies provided by traditional pharmaceutical manufacturer PAPs have the practical effect of locking beneficiaries into the manufacturer's product, even if there are other equally effective, less costly alternatives (and even if the patient's physician would otherwise prescribe one of these alternatives). Subsidizing Medicare Part D cost-sharing amounts will have this same steering effect. Moreover, as we have previously noted in the Part B context, cost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions. We are concerned that pharmaceutical manufacturers may seek improperly to maximize these profits by creating sham "independent" charities to operate PAPs; by colluding with independent charity programs to ensure that the manufacturer's contributions only or primarily benefit patients using its products (discussed in more detail below); or by manipulating financial need or other eligibility criteria to maximize the number of beneficiaries qualifying for cost-sharing subsidies.

These risks are necessarily illustrative, not exhaustive, of the potential risks presented by pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts.

Cost-sharing subsidies offered by a pharmaceutical manufacturer PAP to the dispensing supplier differ in two important respects from a provider's or supplier's unadvertised, non-routine waiver of cost-sharing amounts based on a patient's financial need, which has long been permitted. First, the subsidies result in the dispensing supplier receiving full payment for the product and avoiding the risk of non-collection, thus providing the supplier with an economic incentive to favor the subsidized product and a disincentive to recommend a lower-cost alternative, such as a generic. In addition, the availability of PAP assistance is typically advertised and may influence a beneficiary's choice of product (through the prescribing physician acting on behalf of the beneficiary). Moreover, once a beneficiary is enrolled in a pharmaceutical manufacturer PAP, the beneficiary is effectively locked into using the pharmaceutical manufacturer's product, since the beneficiary risks losing financial assistance if he or she switches products, even if an equally effective, but less expensive, product would be in his or her best medical interests.

A definitive conclusion regarding whether a particular manufacturer PAP violates the anti-kickback statute would require a case-by-case analysis of all of the relevant facts and circumstances, including the intent of the parties. However, for the reasons noted above, we believe that pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts raise substantial concerns under the anti-kickback statute.

B. Independent Charity PAPs

Long-standing OIG guidance makes clear that pharmaceutical manufacturers can effectively contribute to the pharmaceutical safety net by making cash donations to independent, *bona fide* charitable assistance programs.[14]

Under a properly structured program, donations from a pharmaceutical manufacturer to an independent, *bona fide* charity that provides cost-sharing subsidies for Part D drugs should raise few, if any, anti-kickback statute concerns, so long as:

(i) Neither the pharmaceutical manufacturer nor any affiliate of the manufacturer (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) exerts any direct or indirect influence or control over the charity or the subsidy program;

(ii) The charity awards assistance in a truly independent manner that severs any link between the pharmaceutical manufacturer's funding and the beneficiary (*i.e.*, the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer);

(iii) The charity awards assistance without regard to the pharmaceutical manufacturer's interests and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan;

(iv) The charity provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and[15]

(v) The pharmaceutical manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.[16]

[12] *See* 42 CFR 423.329. For purposes of calculating payments under catastrophic coverage, the cost of a beneficiary's drug is based in part on the plan's negotiated price (*i.e.*, a price that is set by the plan based on negotiations with pharmaceutical manufacturers and pharmacies).

[13] *See* 42 CFR 423.329; 42 CFR 423.336.

[14] In-kind donations of drugs to independent charity PAPs pose additional risks not yet directly addressed in prior OIG guidance, and we have insufficient experience with them to offer detailed guidance here. While in-kind donations have the potential benefit of increasing the value of donations (because marginal costs of drugs are generally low), they also have the effect of creating a direct correlation between the donation and use of a particular donor's product, thereby weakening important safeguards of an independent charity PAP arrangement. Moreover, there would appear to be difficult accounting and valuation issues raised by the use of in-kind product to subsidize Part D cost-sharing obligations, both for purposes of calculating TrOOP and for purposes of determining the amount of in-kind drug that equals the Part D cost-sharing amount owed.

[15] We recognize that what constitutes an appropriate determination of financial need may vary depending on individual patient circumstances. We believe that independent charity PAPs should have flexibility to consider relevant variables beyond income. For example, PAPs may choose to consider the local cost of living; a patient's assets and expenses; a patient's family size; and the scope and extent of a patient's medical bills.

[16] We have previously approved a *bona fide* independent charity PAP arrangement that included only limited reporting of *aggregate* data to donors in the form of monthly or less frequent reports containing *aggregate* data about the number of all applicants for assistance in a disease category and the number of patients qualifying for assistance in that disease category. *See* OIG Advisory Opinion No. 02–1. No individual patient information may be conveyed to donors. Moreover, neither patients nor donors may be informed of the donation made to the PAP by others, although, as required by Internal Revenue Service regulations, the PAP's annual report and a list of donors may be publicly available. *See* OIG Advisory Opinion No. 04–15. Reporting of data that is not in the aggregate or that is patient specific would be problematic, as would reporting of any data, whether or not in the

Simply put, the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices.[17]

We recognize that some *bona fide* independent charities reasonably focus their efforts on patients with particular diseases (such as cancer or diabetes) and that some of these charities permit donors to earmark their contributions generally for support of patients with a specific disease. In general, the fact that a pharmaceutical manufacturer's donations are earmarked for one or more broad disease categories should not significantly raise the risk of abuse. However, we are concerned that, in some cases, charities may artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of donor's particular products. For example, we would be concerned if disease categories were defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs, rather than by diagnoses or broadly recognized illnesses or diseases. This type of arrangement would present an elevated risk of fraud and abuse because of the increased likelihood that the PAP would function as an improper conduit for manufacturers to provide funds to patients using their specific drugs. To avoid this risk, pharmaceutical manufacturers should not influence, directly or indirectly, the identification of disease or illness categories,[18] and pharmaceutical manufacturers should limit their earmarked donations to PAPs that define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products.[19]

C. PAPs Operating Outside Part D

CMS has issued guidance stating that PAPs may elect to provide free drugs to financially needy Medicare Part D enrollees outside the Part D benefit.[20] In these circumstances, the beneficiary obtains drugs without using his or her Part D insurance benefit. Beginning when a beneficiary's assistance under a PAP became effective, no claims for payment for any covered outpatient prescription drug provided outside of the Part D benefit may be filed with a Part D plan or the beneficiary, and the assistance must not count toward the beneficiary's TrOOP or total Part D spending for any purpose. For the reasons noted in connection with pharmaceutical manufacturer PAPs discussed above, PAPs that provide assistance outside the Part D benefit only during the coverage gap (*i.e.*, "wrapping around" the Part D benefit) pose a heightened risk of abuse. However, while it is difficult to assess the application of the fraud and abuse laws to PAPs that operate outside Part D absent a specific set of facts, it would appear that PAPs that furnish free outpatient prescription drugs entirely outside the Part D benefit pose a reduced risk under the anti-kickback statute, provided that:

(i) The PAP includes safeguards that ensure that Part D plans are notified that the drug is being provided outside the Part D benefit so that no payment is made for the subsidized drug by any Part D plan and no part of the costs of the subsidized drug is counted toward any beneficiary's TrOOP;

(ii) The PAP provides assistance for the whole Part D coverage year (or the portion of the coverage year remaining after the beneficiary first begins receiving the PAP assistance);[21]

(iii) The PAP assistance remains available even if the beneficiary's use of the subsidized drug is periodic during the coverage year;

(iv) The PAP maintains accurate and contemporaneous records of the subsidized drugs to permit the Government to verify the provision of drugs outside the Part D benefit;

(v) Assistance is awarded based on reasonable, uniform, and consistent measures of financial need and without regard to the providers, practitioners, or suppliers used by the patient or the Part D plan in which the patient is enrolled; and

(vi) The arrangement complies with any then-existing guidance from CMS.

In addition, to promote quality of care, we believe it would be important for PAPs that provide free drugs outside the Part D benefit to coordinate effectively with Part D plans so that the plans can undertake appropriate drug utilization review and medication therapy management program activities.

D. "Coalition Model" PAPs

We are aware of nascent efforts by some in the industry to develop arrangements through which multiple pharmaceutical manufacturers would join together to offer financially needy Part D enrollees a card or similar vehicle that would entitle the enrollees to subsidies of their cost-sharing obligations for the manufacturers' products, typically in the form of discounts off the negotiated price otherwise available to the enrollee under his or her Part D plan. It is premature to offer definitive guidance on these evolving programs. Although these programs would operate so that the manufacturers effectively underwrite only the discounts on their own products, we observe that the risk of an illegal inducement potentially may be reduced if: (i) The program contains features that adequately safeguard against incentives for card holders to favor one drug product (or any one supplier, provider, practitioner, or Part D plan) over another; (ii) the program includes a large number of manufacturers, including competing manufacturers and manufacturers of both branded and generic products, sufficient to sever any nexus between the subsidy and a beneficiary's choice of drug; and (iii) each participating pharmaceutical manufacturer offers subsidies for *all* of its products that are covered by *any* Part D plan formulary. Other safeguards may also be needed to reduce the risk of an improper inducement. Moreover, a program under which Part D enrollees pay a portion of their drug costs out-of-pocket would tend to reduce the risk of abuse by preserving the beneficiary's incentive to locate and purchase equally effective, lower cost drugs.

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aggregate, related to the identity, amount, or nature of subsidized drugs.

[17] For further guidance on establishing compliant independent charity PAPs, see OIG Advisory Opinion Nos. 04–15, 02–1, 98–17, and 97–1 (favorable opinions issued to *bona fide*, independent charities that accept industry funding).

[18] Nothing in this Bulletin should be construed as preventing a charity from obtaining educational materials from donors that the donors generally make available to practitioners or the general public (*e.g.*, clinical information about drug products).

[19] We recognize that, in rare circumstances, there may only be one drug covered by Part D for the diseases in a particular category or only one pharmaceutical manufacturer (including its affiliates) that makes all of the Part D covered drugs for the diseases in a particular category. In these unusual circumstances, the fact that a disease category only includes one drug or manufacturer would not, standing alone, be determinative of an anti-kickback statute violation. Such a determination could only be made on a case-by-case basis after examining all of the applicable facts and circumstances, including the intent of the parties. We note that it would be important for the PAP program to cover additional products or manufacturers as they become available.

[20] *See* CMS Frequently Asked Question ID 6153, *http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=6153* (regarding PAPs providing assistance with Part D drug costs to Part D enrollees outside of the Part D benefit and without counting towards TrOOP).

[21] We note that our position that PAPs operating outside the Part D benefit should provide assistance for the remainder of the coverage year is consistent with our observation in several advisory opinions that manufacturers "may provide free drugs to financially needy beneficiaries, so long as no Federal health care program is billed for all or part of the drugs." OIG Advisory Opinion Nos. 02–13 and 03–3.

IV. Bulk Replacement Models

Bulk replacement" or similar programs, pursuant to which pharmaceutical manufacturers (or their affiliated PAPs) provide in-kind donations in the form of free drugs to pharmacies, health centers, clinics, and other entities that dispense drugs to qualifying uninsured patients, are different from traditional PAPs that provide assistance directly to patients. These programs potentially implicate the Federal anti-kickback statute if the free drugs are given to a recipient that is in a position to generate Federal health care program business for the donor manufacturer. Whether a particular bulk replacement program complies with the fraud and abuse laws would require a case-by-case analysis. In undertaking any analysis, we would consider, among other factors, how the program is structured and whether there are safeguards in place: (i) To protect Federal health care program beneficiaries from being steered to particular drugs based on the financial interests of their health care providers or suppliers; (ii) to protect the Federal health care programs from increased program costs; and (iii) to ensure that bulk replacement drugs are not improperly charged to Federal health care programs. Additionally, bulk replacement as a means of subsidizing only the Medicare Part D cost-sharing amount potentially raises substantial risks related to accounting for the amount of replacement drug that would be equivalent to the cost-sharing amount owed by the beneficiary; properly attributing that amount to specific beneficiaries; and properly calculating TrOOP.

V. Transitioning From Existing Pharmaceutical Manufacturer PAPs

OIG is mindful of the importance of a smooth, effective transition for beneficiaries who are currently participating in pharmaceutical manufacturer PAPs and elect to enroll in Medicare Part D. While most such enrollees are likely to qualify for the low-income subsidies available under Part D, we are concerned that there may not be sufficient independent charity PAPs available before the January 1, 2006 start date of the Part D program to accommodate beneficiaries of limited means who may need an alternative PAP arrangement. We recognize the importance of not unnecessarily burdening or alarming beneficiaries. We believe that manufacturers will play an important role in ensuring an effective transition.

With respect to pharmaceutical manufacturer PAPs that are in existence prior to the date of publication of this Special Advisory Bulletin, during the initial calendar year of the Part D benefit, OIG will take into consideration in exercising its enforcement discretion with respect to administrative sanctions arising under the anti-kickback statute whether the PAP is taking prompt, reasonable, verifiable, and meaningful steps to transition patients who enroll in Part D to alternative assistance models, such as independent charities.

In addition to taking steps to transition beneficiaries to other programs, pharmaceutical manufacturer PAPs can reduce their fraud and abuse exposure by taking one or more of the following steps: (i) Adjusting financial need criteria to reflect the lower drug costs incurred by Part D enrollees (*i.e.*, liability for premiums and cost-sharing amounts only, instead of the total cost of the drugs); (ii) where possible, subsidizing other drugs in the same class as the manufacturer's products covered by the PAP if a beneficiary's physician prescribes an alternate product; and (iii) checking CMS eligibility files, to the extent available, on a reasonably regular basis to determine whether PAP patients have enrolled in Part D and should be transitioned to other assistance programs. Occasional, inadvertent cost-sharing subsidies provided to a Part D enrollee should not be problematic (*e.g.*, where, despite due diligence, a pharmaceutical manufacturer PAP does not know and should not have known that a beneficiary has enrolled in Medicare Part D). Notwithstanding a pharmaceutical manufacturer's compliance with the foregoing, the Government will take enforcement action in cases where there is evidence of unlawful intent.

The potential variability of PAPs, the fact that the Part D program is not yet operational, and the fact that it is not possible to predict all future or potential fraud and abuse schemes with certainty, make it difficult to provide comprehensive general guidance on the application of the anti-kickback statute to PAPs for Part D enrollees at this time. We intend to monitor the situation closely and may issue further guidance, if needed. Nothing in this Bulletin should be construed as precluding any form of lawful assistance not described in this Bulletin.

VI. OIG Advisory Opinion Process

OIG has an advisory opinion process that is available to individuals and entities, including pharmaceutical manufacturers, that want assurance that they will not run afoul of the fraud and abuse laws.[22] OIG advisory opinions are written opinions that are legally binding on OIG, the Department, and the party that requests the opinion. To obtain an opinion, the requesting party must submit a detailed, written description of its existing or proposed business arrangement. The length of time that it takes for OIG to issue an opinion varies based upon a number of factors, including the complexity of the arrangement, the completeness of the submission, and how promptly the requestor responds to requests for additional information. Further information about the process, including frequently asked questions, can be found on the OIG Web page at *http://oig.hhs.gov/fraud/advisoryopinions.html.*

The Office of Inspector General (OIG) was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse, and waste in the Department's programs and to promote efficiency and economy in departmental operations. OIG carries out this mission through a nationwide program of audits, investigations, and inspections. The Health Care Fraud and Abuse Control Program, established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), authorized OIG to provide guidance to the health care industry to prevent fraud and abuse and to promote the highest level of ethical and lawful conduct. To further these goals, OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by OIG.

Daniel R. Levinson,

Inspector General.

[FR Doc. 05–23038 Filed 11–21–05; 8:45 am]

BILLING CODE 4150–04–P

[22] Section 1128D(b) of the Act; 42 CFR part 1008.

DEPARTMENT OF HOMELAND SECURITY

[DHS–2005–0054]

Office of State and Local Government Coordination and Preparedness; SAFER Grant Program

AGENCY: Office of State and Local Government Coordination and Preparedness, DHS.

ACTION: Notice and request for comment.

SUMMARY: Pursuant to the Paperwork Reduction Act, the Department of Homeland Security (DHS) solicited comments on the proposed collection of information in connection with the Staffing for Adequate Fire and Emergency (SAFER) Grant Application.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CMS Perspective
on
Pharmaceutical Company Patient Assistance Programs
January 25, 2006

- The decision to keep a patient assistance program is up to the pharmaceutical company, not the US government. The terms of the programs are determined by the company, without any government involvement.

- There is nothing in the law that prohibits a pharmaceutical company patient assistance program from providing drug assistance to Medicare beneficiaries, even those enrolled in a Medicare prescription drug plan, but that help has to be *outside* the Medicare coverage – just as it has been until now.

- No company needs to end its patient assistance program on account of the drug benefit starting. Lawful avenues exist for pharmaceutical companies and others to help Part D beneficiaries with their drug costs. Pharmaceutical company patient assistance programs may elect to provide free drugs to financially needy Medicare Part D enrollees outside the Part D benefit. In these circumstances, the beneficiary obtains the patient assistance program drugs without using his or her Part D insurance benefit.

- Specifically, pharmaceutical company patient assistance programs **can** provide coverage for particular drugs that are included in the Medicare drug benefit. This assistance would remain independent of the Medicare drug coverage, as it was before 2006. Any assistance a pharmaceutical patient assistance program provides to a Part D enrollee for prescription drugs that would have been covered under his or her Part D plan would not count as an incurred cost that would be applied toward the enrollee's true out-of-pocket costs (known as "TrOOP") balance or total drug expenditures. In other words, beginning when a beneficiary's assistance under a patient assistance program became effective, no claims for payment for any covered outpatient prescription drug provided outside of the Part D benefit may be filed with a Part D plan or the beneficiary, and the assistance must not count toward the beneficiary's TrOOP or total Part D spending for any purpose.

- In fact, a company can continue its patient assistance program at a much lower cost than in the past, because most of the seniors eligible for pharmaceutical company patient assistance programs now have access to very comprehensive coverage through the Medicare program's Limited Income Subsidy.

- Nothing in any Office of the Inspector General (OIG) laws, regulations, or guidance prevents pharmaceutical company patient assistance programs from providing free or reduced price outpatient prescription drugs to uninsured patients and Medicare beneficiaries who have not enrolled in Part D.

- In addition, as outlined more fully in the OIG guidance, lawful avenues exist for pharmaceutical company patient assistance programs to assist financially needy Part D enrollees. The OIG has issued a Special Advisory Bulletin addressing the application of the fraud and abuse laws to pharmaceutical company patient assistance programs (see http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/PAPAdvisoryBlletinFinal-Final.pdf).

    - The Bulletin explains that pharmaceutical companies face a heightened risk of liability under the fraud and abuse laws if they assist Part D enrollees by paying all or a portion of the Part D cost-sharing amounts owed by the Part D enrollees for the company's products. For reasons explained more fully in the OIG's Bulletin, these types of cost-sharing subsidies pose all the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries' incentives to locate and use less expensive, equally effective drugs.

    - The Bulletin also makes clear that pharmaceutical companies may choose to provide free or reduced price drugs to financially needy Part D beneficiaries, so long as the assistance program is properly structured and the free or reduced price drugs are provided entirely outside the Part D benefit. They may also choose to make cash donations to bona fide, independent charities that assist Medicare beneficiaries with drug expenses.

- For example, suppose Ms. Smith has qualified for a patient assistance program for a particular, costly cancer drug. She signs up for Part D for her other medications, but her income and assets are too high to qualify for the Part D low-income subsidy. The pharmaceutical company could continue to provide her cancer drug through their patient assistance program, so that Ms. Smith continues to face the same out-of-pocket costs for the cancer drug as she did before. Ms. Smith would not get coverage from her Part D plan for the cancer drug. Because the pharmaceutical company would only need to provide such coverage for Medicare beneficiaries with incomes that are limited but too high to qualify for the low-income subsidy, the company could continue the assistance program for people like Ms. Smith at a significantly lower cost than before Part D began.

- If a company chooses to do so, it can have a "win-win": significantly lowering the cost of its patient assistance program compared to before the drug benefit, so that it can help more people getting drugs they need, and at the same time they can make sure that all people who have depended on the pharmaceutical company's patient assistance program in the past can get the same or more help.

- OIG guidance states that companies may enter into data sharing agreements with CMS to facilitate plan tracking of beneficiary drug utilization. CMS will work with companies interested in pursuing a data sharing agreement in accordance to the OIG guidance.

Exhibit D

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR BENEFICIARY CHOICES

October 4, 2006

Memorandum To: All Part D Sponsors

Subject: HPMS Q & A - Patient Assistance Programs

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

The following question and answer on patient assistance programs operating outside the Part D benefit has been revised and updated in the Frequently Asked Questions Database on the CMS website at http://questions.cms.hhs.gov.

Q: Can patient assistance programs (PAPs) provide assistance with Part D drug costs to Part D enrollees outside of the Part D benefit and without counting towards TrOOP?

A: We have previously advised that drug payments made by PAPs on behalf of Part D enrollees could count toward TrOOP, unless these organizations qualify as group health plans, insurance or otherwise, or other similar third-party payment arrangements. However, we clarify that we will allow PAPs the option of providing assistance for covered Part D drugs on behalf of Part D enrollees outside the Part D benefit. Under this option, a PAP would operate outside of the Part D benefit, and any assistance it provides to a Part D enrollee for drugs that would have been covered under his or her Part D plan would not count as an incurred cost that would be applied toward the enrollee's TrOOP balance or total drug spend. In other words, when operating outside the Part D benefit (and beginning at the point at which a beneficiary's assistance under a PAP is effective), a claim for the drug for which a PAP had provided assistance would never be submitted to a beneficiary's Part D plan.

Operating outside the Part D benefit does not preclude a PAP sponsor from requiring its enrollees – including those enrolled in a Part D plan – from paying a nominal copayment when they fill a prescription for a covered Part D drug for which they provide assistance. We believe that any copayments assessed by PAPs operating outside the Part D benefit should be nominal, since only nominal beneficiary cost-sharing is consistent with the concept of operating outside Part D. Moreover, given that copayments are typically assessed for purposes of minimizing drug overutilization, the assessment of anything but nominal cost-sharing by PAPs is seemingly inconsistent with the mission of a charitable organization structured to provide assistance with prescription drug costs to low-income patients.

Although PAP payments made for those covered Part D drugs outside the benefit may never count toward enrollees' TrOOP or total drug spend balances, we clarify that any nominal

PAP copayment amounts paid by Part D enrollees will be aggregated to their TrOOP and total drug spend balances, provided the enrollees take responsibility for submitting the appropriate documentation to their plan. It will not be permissible, however, for beneficiary payments structured as administrative fees or premiums to be aggregated to Part D TrOOP and total drug spend balances, as these types of beneficiary out-of-pocket expenditures do not meet the definition of "incurred costs" at 42 CFR 423.100.

Enrollee submission of this documentation is necessary because a PAP operating outside the Part D benefit should never submit a claim for assistance provided for a covered Part D drug to a Part D enrollee's Part D plan. Consistent with our guidance on claims processing, plans should process these enrollee-submitted claims in the order in which they are received, not based on date of service.

As noted elsewhere, in order to facilitate implementation of this policy, plans should establish processes and clear instructions for enrollee paper claim submissions such that they can distinguish between claims submitted for : (1) out-of-network coverage; (2) adjustment to TrOOP balances based on wraparound payments by supplemental payers not previously submitted to the plan; (3) documentation submitted for a purchase made via a discount card or other special cash discount outside the Part D benefit in any applicable deductible or coverage gap phase of the benefit; and (4) documentation submitted for a copayment assessed by a PAP sponsor operating outside the Part D benefit for assistance provided with covered Part D drug costs. We plan to develop and share with plans model paper claims submission forms they can use or revise for these purposes.

The choice of whether to operate inside or outside the Part D benefit would be entirely at each individual PAP's discretion, although the PAP would still need to comply with the Federal fraud and abuse statutes. We note that the issue of establishing criteria for applicability of PAP assistance remains up to each individual PAP. PAPs have discretion to decide at what point financial burden triggers PAP assistance – for example, a set income level or an asset test or a ratio of drug cost to income or assets. [We note, however, that a criterion of being uninsured would be problematic because we do not consider a Part D enrollee in the benefit's coverage gap to be "uninsured" for purposes of a PAP's determination of financial need. Although a Part D enrollee may be required to pay 100 percent cost-sharing until he or she has accrued $3,600 in TrOOP expenditures, that individual continues to have coverage under the Part D plan given his or her access to negotiated prices and continued payment of premiums.]

Once a beneficiary satisfies a PAP's eligibility criteria, however, we believe the PAP should provide assistance through the end of the year. If, for budgetary reasons, a PAP declines to commit to providing assistance through the year, the PAP may decide to limit the amount of drug it will provide to any PAP enrollee. If a PAP decides to set such a cap, such cap should apply uniformly to all PAP enrollees - and not just to Medicare beneficiaries - and should be determined in a manner that is not directly or indirectly related to other drug expenditures by Part D enrollees. PAPs must not employ a cap to terminate PAP assistance in a manner designed to correlate with when the beneficiary's other drug expenditures might suffice to trigger catastrophic coverage under Part D or otherwise as a proxy for when Federal reimbursement would be available for the beneficiary's drugs. (Please refer to Appendix A

for some examples of how TrOOP and total Part D drug spend are affected depending on when enrollment in a capped program takes place and whether an enrollee surpasses the cap in a given coverage year).

The option of operating outside the Part D benefit, with or without the assessment of nominal enrollee copayments for assistance provided, will allow PAP sponsors to continue providing needed assistance to financially needy beneficiaries – those whose incomes are too high to qualify for the low-income subsidy, but whose incomes are low enough that out-of-pocket costs on drugs are still burdensome – while allowing the individual PAPs flexibility to determine the form of their donations and, if operated with sufficient safeguards, to use existing PAP programs to assist needy beneficiaries. We note, however, that we will be monitoring the impact of this guidance and reserve the right to revise it for future plan contract years..

We also emphasize that the most effective – and, ultimately, for the beneficiary, the safest – way for PAPs to operate outside the Part D benefit would involve front-end data exchanges with CMS through the use of PAP-specific trading partner agreements, which we will provide further information about in forthcoming guidance. General information about eligibility file exchange with supplemental payers and other entities is provided in our coordination of benefits guidance. To the extent that a PAP exchanges eligibility files with us, we will be able to flag it as a non-TrOOP eligible payer for the particular Part D drugs it provides Part D enrollees at no cost. This information would therefore be available to plans through the TrOOP facilitation process, and plans would be alerted to the fact that they must follow up with the PAP to identify the prescription drug provided outside the benefit. This, in turn, would allow plans to set their systems to recognize that drug as part of a patient's profile, while setting systems edits to prevent any payment for that prescription. As a result, a beneficiary will be able to obtain free product through the PAP without affecting either TrOOP or total drug spend amounts on plan PDE records. As a result of the data exchange process, the PAP will also receive information regarding its enrollees' Part D enrollment status.

To address safety concerns associated with prescription drugs provided outside the Part D benefits, the front-end data exchange process will enable, as described above, plans to follow-up with PAPs to identify those Part D drugs an enrollee is receiving outside the Part D benefit. This will facilitate plans' provision of required drug utilization review and, if applicable, medication therapy management program activities. If a PAP did not exchange information with CMS in the manner outlined above, such information would remain unknown to the plan, which could potentially lead to quality of care issues. For these reasons, we strongly encourage PAPs wishing to operate outside the Part D benefit participate in this process. Alternatively, a PAP could provide its enrollees with a notice they could provide to their Part D plans indicating that they are receiving one or more drug products from that PAP.

PAP sponsors, whether operating inside or outside the Part D benefit, remain responsible for complying with relevant fraud and abuse laws, including the anti-kickback statute. Liability under the anti-kickback statute requires a case-by-case analysis of the particular facts and circumstances, including the intent of the parties. However, to the extent that PAPs choose to operate within the Part D benefit, generally, the least problematic way of providing

assistance with the costs of covered Part D drugs to Part D enrollees is through support of independent PAPs operated by bona fide public charities without regard to donor interests. Properly structured, these programs can offer an alternative that reduces the risk of fraud or abuse. Among other things, the charity must make an independent determination of patient need, and the patient's receipt of assistance may not depend directly or indirectly on the patient's use of any particular product or supplier of drugs.

We have also received inquiries about the ability of PAPs to pay Part D premiums on behalf of enrollees or to provide free or discounted product through a coalition of manufacturers. Nothing in CMS rules and regulations prohibit such arrangements. We also note that organizations or entities offering patient assistance programs must comply with all relevant fraud and abuse laws, including, when applicable, the Federal anti-kickback statute and the civil monetary penalty prohibiting inducements to beneficiaries. The HHS Office of the Inspector General (OIG) enforces Federal fraud and abuse statutes, and all questions regarding the compliance of specific arrangements with these statutes should be referred to the OIG.

Examples of Impact on TrOOP and Total Part D Drug Expenditures in Capped Patient Assistance Programs

Scenario 1: Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP X. PAP X does not impose any nominal beneficiary cost-sharing, but finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning January 1, 2007. Mrs. Jones uses $2,500 worth of free Drug ABC in 2007.

Donated Product	Dollar Value of Donated Product	Dollar Value of Donated Product Utilized	Impact on Total Drug Spend	Impact on TrOOP
ABC	$5000	$2500	$0	$0

Scenario 2: Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP X. PAP X does not impose any nominal beneficiary cost-sharing, but finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning March 1, 2007. Mrs. Jones purchases $1,265 worth of Drug ABC between January 1 and March 1, 2007 and purchases no additional covered Part drugs. She then uses $2,500 worth of free Drug ABC between March 1 and December 31, 2007.

Donated Product	Dollar Value of Donated Product	Dollar Value of Donated Product Utilized	Impact on Total Drug Spend	Impact on TrOOP
ABC	$5000	$2500	$1265	$515 ($265 deductible plus 25% coinsurance on $1000)

Scenario 3: Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP Y. PAP Y imposes nominal cost-sharing of $5 for each prescription filled, and finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning March 1, 2007. Mrs. Jones purchases $1,265 worth of Drug ABC between January 1 and March 1, 2007 and purchases no additional covered Part D drugs. She then uses $2,500 worth of free Drug ABC between March 1 and December 31, 2007. PAP Y imposes $50 of nominal beneficiary cost-sharing ($5 for each of 10 fills) between March 1 and December 31, 2007. Mrs. Jones submits the appropriate documentation to her PDP for all the nominal copayments assessed by the plan so that they may be aggregated to her TrOOP and total drug spend balances.

Donated Product	Dollar Value of Donated Product	Dollar Value of Donated Product Utilized	Impact on Total Drug Spend	Impact on TrOOP
ABC	$5000	$2500	$1315 ($1265 of total drug spend prior to March 1, 2007, plus $50 in nominal PAP copayments)	$565 ($265 deductible, plus 25% coinsurance on $1000, plus $50 in nominal PAP copayments)

Scenario 4: Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP X. PAP X does not impose any nominal beneficiary cost-sharing, but finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning May 15, 2007. Mrs. Jones purchases $1,265 worth of Drug ABC between January 1 and May 15, 2007, and she purchases no additional covered Part D drugs. She then uses $5,000 worth of free Drug ABC between May 15 and November 1, 2007. Since she has reached PAP X's spending cap for Drug ABC, she begins to use her Part D benefit again for Drug ABC beginning November 1, 2007. She purchases $1,000 worth of Drug ABC between November 1 and December 31, 2007 (during this time period, she is in the coverage gap of the standard defined benefit given use of other covered Part D drugs throughout the year).

Donated Product	Dollar Value of Donated Product	Dollar Value of Donated Product Utilized	Impact on Total Drug Spend	Impact on TrOOP
ABC	$5000	$5000	$2265	$1515 ($265 deductible

				plus 25% coinsurance on 1st $1000 plus $1000 in coverage gap)

Please contact Alissa DeBoy at (410) 786-6041 if you have any questions about this guidance.